

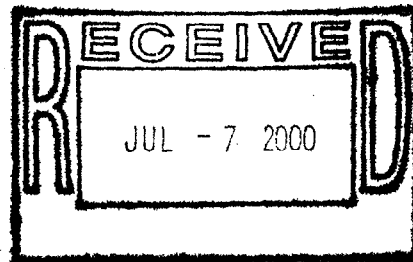
BIOCODEX, Inc.

1910 Fairview Avenue East, Suite 208
Seattle, Washington 98102-3699
(206) 322-5663 FAX (206) 323-2968

00 AUG -8 P2:28

July 1, 2000

VIA COURIER



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

RE: New dietary supplement: Florastor™

Dear CFSAN:

Enclosed please find an original and two copies of "Notification of Marketing Dietary Supplement" submitted pursuant to section 101.93 of the Federal Food, Drug, and Cosmetic Act, on behalf of Biocodex, Inc.

Thank you for your attention to this matter. If you have any questions relating to the notification, please do not hesitate to call me at the above number.

97S-0162

LET 5677

July 1, 2000

**Notification of the Marketing
of a new Dietary Supplement**

Florastor™

Pursuant to section 21CFR101.93 of the Federal Food, Drug, and Cosmetic Act, Biocodex, Inc., located at 1910 Fairview Avenue East, Suite 208, Seattle, WA 98102, hereby notifies the Food and Drug Administration that it has marketed the new dietary supplement, Florastor™, on June 8, 2000. Florastor™ is an encapsulated lyophilized powder of *Saccharomyces boulardii*.

I. Dietary Supplements containing *Saccharomyces boulardii*.

Biocodex, Inc. will market Florastor™ for use in dietary supplements at a maximum level of 200 mg/day. The labeling of Florastor™ states that it is for use in maintaining the balance of intestinal flora and promoting intestinal health.

II. Evidence of Safety

Florastor™, when used under the conditions recommended in the indicated labeling, is reasonably expected to be safe. The active ingredient, *Saccharomyces boulardii*, has been used extensively in Europe at this dose level since 1950 with an excellent tolerance profile.^{1,2} Other products containing the identical active ingredient are currently marketed in foreign countries.³

III. Manufacturer

Florastor™ is manufactured and packaged by Laboratoires Biocodex, 1 Avenue Blaise-Pascal, BP 753, 60007 Beauvais Cedex, France. Florastor™ is imported and distributed by Biocodex, Inc., 1910 Fairview Avenue East, Suite 208, Seattle, WA 98102.

IV. Health Claim

The label on Florastor™ states that it "maintains balance of intestinal flora" and it "promotes intestinal health." No claims to diagnosis, treat, cure or prevent any disease is made.

¹ McFarland LV, Bernasconi P. *Saccharomyces boulardii*: a review of an innovative biotherapeutic agent. Microbial Ecology in Health and Disease 1993;6:157-71.

² Elmer GW, Surawicz CM, McFarland LV. Biotherapeutic agents. A neglected modality for the treatment and prevention of selected intestinal and vaginal infections. JAMA 1996;275:870-6.

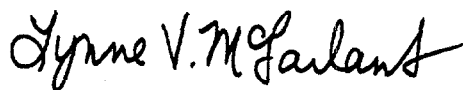
³ Vandenplas Y. Bacteria and yeasts in the treatment of acute and chronic infectious diarrhea. Part II: Yeasts. Clin Microbiol Infect 1999;5:389-95.

V. Active Ingredient

The active ingredient of Florastor™ is *Saccharomyces boulardii*, a nonpathogenic fungus. No other dietary ingredient is contained in the supplement.

VI. Responsible Party

Pursuant to section 21CFR101.93(c) of the Federal Food, Drug, and Cosmetic Act, I, the undersigned, certify that the information contained in the notice is complete and accurate, and that Biocodex, Inc. has substantiation that the above statements are truthful and not misleading.



Lynne V. McFarland, Ph.D.
Director of Scientific Affairs


Enclosures: Panels from the Florastor™ product container

cc: Bernard Hublot, Laboratoires Biocodex

☐ "FDAFlorNotice1.doc"

Front
of
box →


Keep your intestinal tract on track with Florastor.™



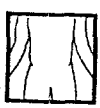
Florastor™

Saccharomyces boulardii from Biocodex

Intestinal Dietary Supplement

MADE IN FRANCE *by a pharmaceutical laboratory* ALL NATURAL  40 CAPSULES

Back
of
box →



If you know that your intestines are sensitive...

Florastor™

- > **Maintains balance of intestinal flora**
Your intestines contain billions of bacteria and types of yeast, called "flora," which are sensitive to changes in diet and stress. During periods of disruption, Florastor helps maintain normal balance of the intestinal flora.
- > **Promotes intestinal health**
The active ingredient in Florastor helps the flora to protect your intestinal tract and keep your intestines functioning well.

Statements on this package have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Manufactured by Laboratories Biocodex, France
Imported by Biocodex, Inc., Seattle, WA

Supplement Facts

Serving Size 2 Capsules
Servings Per Container 20

Amount Per Capsule	
Saccharomyces boulardii from Biocodex	50mg*

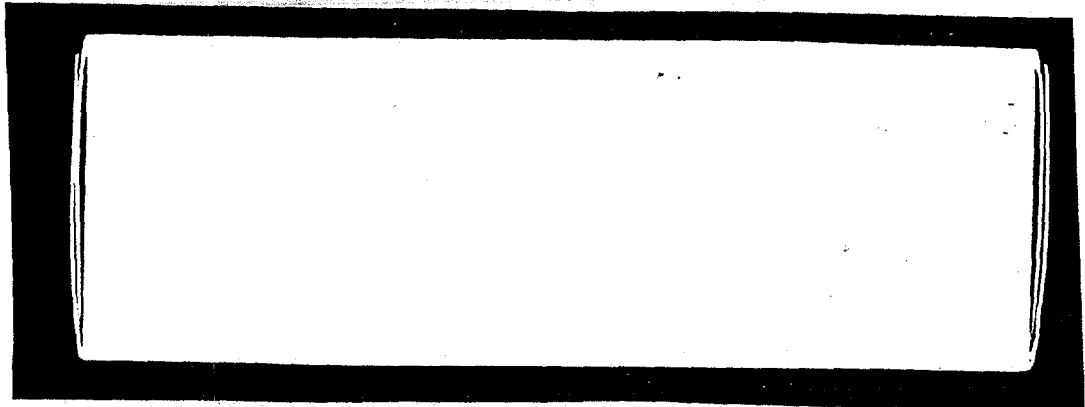
*Daily Value (DV) not established
50mg contains over 1x10⁹ live cells per capsule.

Directions for use:
Take 2 capsules in the morning and 2 capsules in the evening.

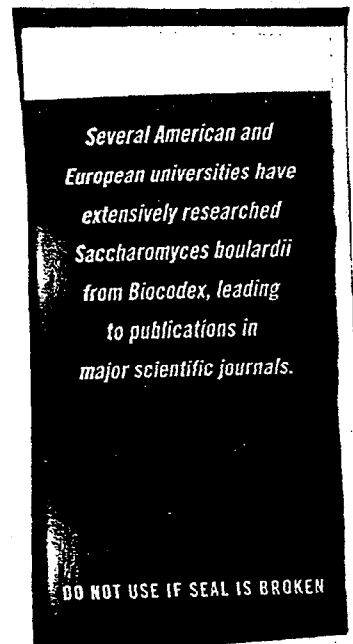
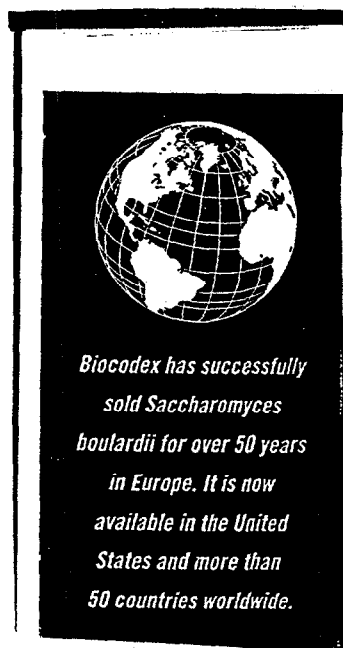
Do not take this product if you are allergic to yeast.

For product information contact:
Biocodex, Inc.
1910 Fairview Ave. E, #208
Seattle, WA 98102
(877) FLORSTR www.florastor.com

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